

As part of the process of issuing this final guidance, FDA has also taken into consideration the Citizen Petition filed on behalf of Americans for Homeopathy Choice received by FDA on June 5, 2020, the reasoning set forth in FDA's response to that Petition, and the references cited therein. And as part of the process of issuing FDA's response to that Petition, FDA has taken into consideration the comments received on the original and revised draft guidances, the reasoning set forth in this final guidance, and the references cited therein.

This final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: December 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022-26567 Filed 12-6-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters; Meeting

AGENCY: Office of the Assistant Secretary for Strategic Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The National Advisory Committee on Children and Disasters (NACCD or the Committee) is required by section 2811A of the PHS Act, as amended by the Pandemic and All

Hazards Preparedness and Advancing Innovation Act (PAHPAIA) and governed by the provisions of the Federal Advisory Committee Act (FACA). The NACCD shall evaluate issues and programs and provide findings, advice, and recommendations to the Secretary of HHS and ASPR to support and enhance all-hazards public health and medical preparedness, response, and recovery aimed at meeting the unique needs of children and their families across the entire spectrum of their wellbeing. The Secretary of HHS has formally delegated authority to operate the NACCD to ASPR.

DATES: The NACCD will conduct a public meeting (virtual) on January 18, 2023 to discuss, finalize and vote on an initial set of recommendations to the HHS Secretary and ASPR regarding challenges, opportunities, and priorities for national public health and medical preparedness, response and recovery, specific to the needs of children and their families in disasters. A more detailed agenda and meeting registration link will be available on the NACCD meeting website <https://www.phe.gov/Preparedness/legal/boards/naccd/Pages/default.aspx>.

ADDRESSES: Members of the public may attend the meeting via a toll-free phone number or Zoom teleconference, which requires pre-registration. The meeting link to pre-register will be posted on <https://www.phe.gov/Preparedness/legal/boards/naccd/Pages/default.aspx>. Members of the public may provide written comments or submit questions for consideration to the NACCD at any time via email to NACCD@hhs.gov. Members of the public are also encouraged to provide comments after the meeting.

FOR FURTHER INFORMATION CONTACT:

Zhoowan Jackson, NACCD Designated Federal Officer, Office of the Assistant Secretary for Strategic Preparedness and Response (ASPR), Department of Health and Human Services (HHS), Washington, DC; 202-205-4217, NACCD@hhs.gov.

SUPPLEMENTARY INFORMATION: The NACCD invites those who are involved in or represent a relevant industry, academia, health profession, health care consumer organization, or state, Tribal, territorial, or local government to request up to four minutes to address the committee live via Zoom. Requests to provide remarks to the NACCD during the public meeting must be sent to NACCD@hhs.gov at least 15 days prior to the meeting along with a brief description of the topic. We would specifically like to request inputs from

the public on disaster behavioral health, COVID-19 pandemic lessons learned and other challenges, opportunities, and strategic priorities for national public health and medical preparedness, response and recovery specific to the needs of children and their families in disasters

Dawn O'Connell,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2022-26561 Filed 12-6-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Drug Abuse Special Emphasis Panel; Production of Cannabis and Related Materials for Research.

Date: January 6, 2023.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, National Institute on Drug Abuse, 301 North Stonestreet Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Preethy Nayar, Ph.D., M.B.B.S., Scientific Review Officer, Scientific Review Branch, National Institute on Drug Abuse, NIH, 301 North Stonestreet Avenue, MSC 6021, Bethesda, MD 20892, (301) 443-4577, nayarp2@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards; 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: December 2, 2022.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022-26611 Filed 12-6-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Information on Proposed Simplified Review Framework for NIH Research Project Grant Applications

AGENCY: National Institutes of Health, HHS.

ACTION: Request for information.

SUMMARY: The purpose of this Request for Information (RFI) is to solicit public input on a proposed revised framework for evaluating and scoring peer review criteria for National Institutes of Health (NIH) research project grant (RPG) applications. NIH is proposing a revised simplified framework that will reorganize five major regulatory criteria under three scored categories and reduce the number of non-score driving review considerations that reviewers evaluate in judging the scientific merit of RPG applications. The proposed changes pertain to those RPGs with standard review criteria. All the factors required by regulation will continue to be evaluated. NIH is not proposing to revise the regulatory criteria. Rather, NIH is proposing to revise its policy of how peer reviewers score the criteria, and how NIH organizes the criteria for review purposes. NIH believes that these changes will allow peer reviewers to refocus on the critical task of judging scientific merit and will improve those judgements by reducing bias.

DATES: The RFI is open for public comment for a period of 90 days. Comments must be received by 11:59:59 p.m. (ET) on March 10, 2023, to ensure consideration.

ADDRESSES: Submissions can be sent electronically to <https://rfi.grants.nih.gov/?s=638509b5409baa49f803e572>. NIH is specifically requesting public comment on the Proposed Revised Simplified Review Framework, a proposed revised framework for evaluating and scoring peer review criteria for NIH research project grant applications, described above. Response to this RFI is voluntary.

FOR FURTHER INFORMATION CONTACT: Questions about this request for information should be directed to Office of Extramural Research, Dr. Kristin

Kramer, Phone number (301) 437-0911, Email simplifiedreview@nih.gov.

SUPPLEMENTARY INFORMATION:

Current Process

The first stage of NIH peer review serves to provide expert advice to NIH on the scientific and technical merit of grant applications. The NIH peer review regulations at 42 CFR part 52h.8 state that for research project grant applications, the scientific peer review group shall assess the overall impact that the project could have on the research field involved, taking into account, among other pertinent factors:

(a) The significance of the goals of the proposed research, from a scientific or technical standpoint;

(b) *Approach:* The adequacy of the approach and methodology proposed to carry out the research;

(c) *Innovation:* The innovativeness and originality of the proposed research;

(d) *Investigator(s):* The qualifications and experience of the principal investigator and proposed staff;

(e) *Environment:* The scientific environment and reasonable availability of resources necessary to the research;

(f) The adequacy of plans to include both genders, minorities, children and special populations as appropriate for the scientific goals of the research;

(g) The reasonableness of the proposed budget and duration in relation to the proposed research; and

(h) The adequacy of the proposed protection for humans, animals, and the environment, to the extent they may be adversely affected by the project proposed in the application.

By NIH policy at: https://grants.nih.gov/grants/policy/nihgps/HTML5/section_2/2.4.1_initial_review.htm# Addition, peer reviewers are currently also required to evaluate Biohazards, Resubmissions, Foreign Organizations, Select Agents, Resource Sharing Plans, and Authentication of Key Biological and/or Chemical Resources. NIH currently gives the first five of the regulatory factors the following categorical labels: Significance, Approach, Innovation, Investigator(s), and Environment.

The NIH peer review regulation does not address scoring. Scoring of all regulatory factors is determined by NIH policy. Currently, peer reviewers provide an Overall Impact Score (scored 1-9) that reflects the overall scientific and technical merit of the application and individual criterion scores for Significance, Investigators, Innovation, Approach, and Environment. The remaining factors, Protections for Human Subjects, Inclusion, Vertebrate Animals, Biohazards, Resubmission,

Renewal, and Revision are evaluated and factored into the Overall Impact Score; however, they are not given individual scores. When reviewers judge any of these to be unacceptable, they are asked to provide justification for that assessment. Beyond these factors, reviewers are asked to assess the following additional review considerations, but these considerations are not considered when reviewers determine an Overall Impact Score: Applications from Foreign Organizations, Select Agents, Resource Sharing Plans, Authentication of Key Biological and/or Chemical Resources, Budget & Period of Support.

Proposal Development

NIH gathered input from many sources in forming this proposal. Unsolicited comments over a period of years, reflecting sustained concerns from reviewers and applicants regarding complexity of review criteria, administrative load, and potential biases led the Center for Scientific Review (CSR) to form a working group to the CSR Advisory Council. To inform that group, CSR published a Review Matters blog at: <https://www.csr.nih.gov/reviewmatters/2020/02/27/seeking-your-input-on-simplifying-review-criteria/> which was cross-posted on the Office of Extramural Research blog, Open Mike at: <https://nexus.od.nih.gov/all/2020/02/27/seeking-your-input-on-simplifying-review-criteria/>. The blog received more than 9,000 views by unique individuals and over 400 comments. The working group presented interim recommendations at: https://public.csr.nih.gov/sites/default/files/2019-10/Review_criteria_wg_CSRAC_interim_report_7April2020.pdf to the CSR Advisory Council, which adopted the recommendations, at public CSR Advisory Council meetings (March 2020 video <https://videocast.nih.gov/summary.asp?live=35649&bhcp=1&start=4307>, slides https://public.csr.nih.gov/sites/default/files/presentations/200330/Simplifying_Review_Criteria_Workgroup_Interim_Rpt_final.pdf; March 2021 video <https://videocast.nih.gov/watch=41574&start=4816>, slides https://public.csr.nih.gov/sites/default/files/2021-04/Simplifying_Review_Criteria_29_March_2021.pdf). Final recommendations from the CSR Advisory Council (report https://public.csr.nih.gov/sites/default/files/2021-04/Recommendations_of_the_CSRAC_Working_Group_on_Simplifying_Review-non-CT_and_CT.pdf) were considered by the CSR Director, as well as major internal NIH extramural-focused committees that included leadership from across NIH